

TRICVALVE[®] TRANSCATHETER BICAVAL VALVES SCREENING PROTOCOL

INCLUSION CRITERIA

- ✓ 18 years and older
- ✓ Patient with severe symptomatic tricuspid regurgitation demonstrated by echocardiography with significant backflow in the lower (IVC) and/or upper (SVC) vena cava and with a v-wave ≥ 25 mmHg as demonstrated by right heart catheterization (measured in the IVC and/or SVC 2-4 cm above/ below RA inflow) within 8 weeks prior to the implantation
- ✓ Suitable for TricValve[®] implantation according to anatomic criteria by computed tomography
- ✓ The patient must have severe, tricuspid regurgitation leading to NYHA class III or IV
- ✓ The patient has LVEF $\geq 30\%$
- ✓ The patient shall be screened by a “Heart Team” – including an interventional cardiologist, cardiothoracic surgeon, and agreed as a candidate for the TricValve[®] Transcatheter Bicaval Valve System implantation
- ✓ Patient/authorized legal guardian understands the nature of the procedure, is willing to comply with associated follow-up evaluations, and provides written informed consent

EXCLUSION CRITERIA

- ✓ Known significant intracardiac shunt (e.g. ventricular septal defect) or congenital structural heart disease based on heart teams decision
- ✓ Requirement for other elective cardiac procedures e.g. PCI (percutaneous treatment of coronary artery) or CABG (coronary artery bypass surgery) up to 90 days after the procedure or 30 days before the procedure
- ✓ Right ventricular failure (TAPSE ≤ 13 mmHg)
- ✓ Systolic pulmonary arterial pressure > 65 mmHg as assessed by Doppler echocardiography
- ✓ Liver cirrhosis Child C